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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,960	12/03/2003	James P. Beckham	14673-028C1	4367

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EXAMINER

CAMPBELL, VICTORIA P

ART UNIT	PAPER NUMBER
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3763

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/726,960	Applicant(s) BECKHAM, JAMES P.	
	Examiner VICTORIA P. CAMPBELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the first fiber layer, second fiber layer, binding layer, and adhesive layer must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 4 recites the limitation "an adhesive layer" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim, as applicant has already claimed a "binding layer" in claim 1, from which claim 4 depends, and applicant appears to have no support for a binding layer and an adhesive layer in the specification. Accordingly, the examiner has interpreted "adhesive layer" to be the same layer as the "binding layer" and therefore claim 4 fails to further limit the independent claim.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of copending Application No. 10/726,464 and claims 1-36 of copending Application No. 10/954,866. Although the conflicting claims are not identical, they are not patentably distinct from each other because all claims in the copending applications appear to be drawn to the same scope of subject matter: a non-compliant balloon having at least a first fiber layer having a first fiber, and a second fiber layer having a second fiber, wherein the first and second fibers form an angle. Further limitations, including a binding layer and particulars about the thickness of fibers and the density of their windings are consistent through the applications, as well as the balloon being non-compliant, either described as longitudinal length or interior surface area remaining unchanged or indicating that the fibers themselves are non-compliant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

7. Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

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required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

8. Claim 4, as described above, contains reference to an adhesive layer. As indicated above, the examiner has interpreted adhesive layer to be commensurate in scope to the binding layer of claim 1 and therefore claim 4 does not further limit the scope of claim 1.

9. The use of the trademarks has been noted in this application, most notably in claim 25 (Kevlar, Dacron, etc). These should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,797,877 to Hamilton et al in view of WO 95/18647 to Rau et al.

Regarding claims 1-17, Hamilton et al teach a non-compliant medical balloon (24; Col. 3, lines 3-4) which may be inflated and deflated with fluid (Col. 3, lines 7-10) having an interior surface area which does not change during inflation (the balloon is adhered to the catheter at ends 26 and 28 and is non-compliant, therefore it's interior surface area will not change), further comprising a first layer (34b) and a second layer (36b) and a binding layer (42) which secures the first layer to the second layer and prevents relative motion between the two during inflation and deflation. Hamilton et al further teach that the binding layer is a polymeric coating which may be a polymer or copolymer (Col. 6, lines 20-26). Hamilton et al do not, however, explicitly teach that the first or second layer contain fibers.

Rau et al teach the reinforcement of polymeric balloon structures using non-compliant fibers which would impart a tensile strength along any axis in which they were used. These filaments may be used individually or may be woven together or aligned in parallel on the outside of the balloon structure. (See Page 14, line 25-Page 15, line 12.) At the time of invention, it would have been obvious to one having ordinary skill in the art to use the filament-reinforced layers of Rau et al in the balloon of Hamilton et al because both references teach use of non-compliant, biocompatible materials for use in balloon catheters, and the substitution of one material for the other would achieve the

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predictable result of forming a medical balloon which would not expand beyond a predetermined dimension upon inflation.

Regarding claims 18-33, Hamilton et al teach a non-compliant medical balloon (24; Col. 3, lines 3-4) which may be inflated and deflated with fluid (Col. 3, lines 7-10), further comprising a base layer (34b) and a film (36b) which secures the first layer to the second layer and prevents relative motion between the two during inflation and deflation. Hamilton et al further teach an adhesive layer (42) which, when coated over the base layer, would hold anything between it and the base layer to the base. Hamilton et al do not, however, explicitly teach first or second fibers.

Rau et al teach the reinforcement of polymeric balloon structures using non-compliant fibers which would impart a tensile strength along any axis in which they were used. These filaments may be used individually or may be woven together or aligned in parallel on the outside of the balloon structure. (See Page 14, line 25-Page 15, line 12.) Rau et al further teach placing these fibers into polyimide films (Page 15, lines 10-12). At the time of invention, it would have been obvious to one having ordinary skill in the art to use the filament-reinforced layers of Rau et al in the balloon of Hamilton et al because both references teach use of non-compliant, biocompatible materials for use in balloon catheters, and the substitution of one material for the other would achieve the predictable result of forming a medical balloon which would not expand beyond a predetermined dimension upon inflation.

Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to orient the fibers along the axis which required the

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most control. Seeing as Hamilton et al disclose a balloon that is completely non-compliant, it would have been obvious to one using the teaching of Rau et al as described above to orient the fibers in the separate layers such that they cross and reinforce the balloon in all dimensions. It would have also been obvious to one having ordinary skill in the art at the time the invention was made to orient the fibers at or near eighty degrees or a right angle, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

The thickness of the fibers themselves being approximately 0.0005 inches is obvious in view of Rau et al, which teaches that the layers of the balloon may be of 0.0003-0.003 inches thick. One having ordinary skill in the art would therefore use a fiber having a thickness which was within the same range and generally thinner in diameter than the wall itself in order that the fiber is inlaid into the balloon as described in Page 15, lines 10-12. 0.0005 inches most certainly falls within this expected range.

Regarding the winding density of the fibers of the second layer, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use this or any winding density, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding the placement of a third fiber layer atop the second fiber layer, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a third fiber layer, since it has been held that mere duplication of the

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essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding the materials of claims 25 and 27, Hamilton teaches the use of PBT as a non-compliant material for the balloon (Col. 3, lines 56-58), thus it would have been obvious to use in the fibers, and that the base layer can be comprised of PET (Col. 3, lines 21-22).

Response to Arguments

13. Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. USPN 5,066,285 to Hillstead and USPN 5,453,076 to Kiyota et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

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